UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

ERICA SCHULZE, **Plaintiff,** **vs.** **ETHICON, INC. and JOHNSON & JOHNSON,** **Defendants.**	**MEMORANDUM DECISION AND ORDER** **Case No. 1:22CV26 DAK-JCB** **Judge Dale A. Kimball**

This matter is before the court on Defendants' Motion for Partial Dismissal of First Amended Complaint. On March 16, 2023, the court held a hearing on the motion via Zoom videoconferencing. At the hearing, Jeffrey Allen represented Plaintiff and Jin Yoshikawa and Lauren E.H. DiFrancesco represented Defendants Ethicon, Inc. and Johnson & Johnson. At the conclusion of the hearing, the court took the motion under advisement. The court has carefully considered the memoranda filed by the parties, the arguments made by counsel at the hearing, and the law and facts pertaining to the motions. Now being fully advised, the court issues the following Memorandum Decision and Order granting Defendants' Motion for Partial Dismissal of First Amended Complaint.

BACKGROUND

This is a pelvic mesh product liability case in which Plaintiff Erica Schulze alleges that she sustained injuries from the implantation of TVT-O, a prescription medical device manufactured by Defendant Ethicon, Inc. for the surgical treatment of stress urinary incontinence ("SUI"). Plaintiff's First Amended Complaint (FAC) asserts three causes of action sounding in negligence

and strict liability. Her first cause of action is for negligence; her second cause of action is for strict liability/design defect, and her third cause of action is for strict liability/failure to warn. This motion pertains only to her first cause of action for negligence.

Plaintiff's negligence cause of action is based on theories of negligent design defect, manufacturing defect, and failure to warn, along with other arguably unrecognized negligence theories (within a products liability context), such as failure to test, inspect, train, study, and conduct adequate post-market vigilance or surveillance of the TVT-O.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Defendants") ask the court to limit Plaintiff's negligence claim to negligent design defect and failure to warn theories and to dismiss any other negligence theories asserted by Plaintiff (i.e., failure to test, inspect, train, study, and conduct adequate post-market vigilance or surveillance of the TVT-O).[1]

Plaintiff argues that her negligence claims should not be limited to design defect and failure to warn theories, asserting that she should be able to assert other theories of negligence, such as failure to test, inspect, train, study, and conduct adequate post-market vigilance or surveillance of the TVT-O.

LEGAL STANDARD

"To survive a motion to dismiss [under Rule 12(b)(6)], a complaint must contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face.

[1] In response to Defendants' motion, Plaintiff has withdrawn her manufacturing defect claim but has reserved "the right to seek leave to allege such a claim if sufficient evidence is identified during discovery." *See* ECF No. 22, at 1 n.1. Accordingly, the manufacturing defect claim is dismissed.

A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendants are liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In reviewing a motion to dismiss, the court assumes the truth of "all well-pleaded facts in the complaint, and draw[s] all reasonable inferences therefrom in the light most favorable to the plaintiffs." *Dias v. City & Cty. of Denver*, 567 F.3d 1169, 1178 (10th Cir. 2009).

DISCUSSION

Utah law recognizes three types of product defects: design defects, manufacturing flaws, and inadequate warnings regarding use. *Grundberg v. Upjohn Co.*, 813 P.2d 89, 92 (Utah 1991); *Bishop v. GenTec, Inc.*, 2002 UT 36, ¶¶ 24-26 ("allegations of negligence contained in a claim for products liability do not transform the claim into one for ordinary negligence."); *Gudmundson v. Del Ozone*, 2010 UT 33, ¶ 45, 232 P.3d 1059, 1070 (quoting *Bishop*); *see also Brown v. Sears, Roebuck & Co.*, 328 F.3d 1274, 1283 (10th Cir. 2003) (stating that "our task here is to follow Utah law, and we are bound by [Utah Code Ann.] § 78–15–6(2)," in determining that negligence claims are limited to product defects).[2] Other judges in the District of Utah have recognized that negligence claims pertaining to products are limited to theories of design defects, manufacturing flaws, and inadequate warnings. *Barben v. Beretta USA Corp.*, No. 1:16-CV-00094-DN, 2017 WL 6501850, at *7 (D. Utah Dec. 18, 2017); *Tuttle v. CIBA Vision Corp.*, No. 2:05-CV-340 TS, 2007 WL 677134, at *1 (D. Utah Mar. 1, 2007).

[2] Utah Code Ann. § 78–15–6 has been renumbered as § 78-7-703.

There is no question that Plaintiff may pursue both negligence and strict liability claims regarding an allegedly defective product. *See Utah Local Government Trust v. Wheeler Machinery Co*., 199 P.3d 949, 951 (2008); *Silze v. Stanley-Bostitch*, 1999 UT 20, ¶ 8, 979 P.2d 317 (1999). The only question at issue in this motion is whether Plaintiff can pursue various theories of negligence that do not appear to be recognized under Utah products liability law—or that are necessarily subsumed within the recognized theories of design defect or failure to warn.

Other courts that have explicitly addressed this issue have determined that these negligence theories are either not recognized under their respective state's law—or they are subsumed within the three recognized claims. See, *e.g.*, *Rodgriguez v. Stryker Corp.*, 680 F.3d 568, 574 (6th Cir. 2012) (failure to test claim "collapses into the failure-to-warn" claim); *Dupere v. Ethicon, Inc.*, No. 21CV2605 (DLC), 2022 WL 523604, at *3 (S.D.N.Y. Feb. 22, 2022) (holding failure to test is not a recognized theory of liability); *Howe v. Ethicon, Inc.*, No. 21-CV-2031 (NSR), 2022 WL 2316375, at *4 (S.D.N.Y. June 27, 2022) (same).

In *Dupere v. Ethicon, Inc.*, a case similar to the instant case, the court found that New York law did not recognize an independent theory based on a failure to test, and it also noted that the Third Statement of Torts defines only three activities creating product liability: *liability* for a manufacturing defect due to a defect in design, the manufacturing process, or in a failure to warn. *Dupere*, No. 21CV2605 (DLC), 2022 WL 523604, at *3-4 (S.D.N.Y. Feb. 22, 2022) (citing Restatement (Third) of Torts: Prod. Liab. § 2 (1998) ("R.3d Torts"). The court also recognized that the *American Jurisprudence* treatise explicitly adopts the Restatement's formulation and

describes a products liability action as addressing "a defect in a product" that consists of "a mistake in manufacturing, improper design, or the inadequacy or absence of warnings regarding the use of the product." *Id*. (citing 63 Am. Jur. 2d Products Liability § 10 (2022)). The *Dupere* court explained that:

> Of course, evidence of a testing regimen or its absence may be submitted in connection with a particular claim, for instance to defend against or support a claim of negligence in product design. But negligent testing is not an independent products liability claim. *See, e.g*., R.3d Torts § 2 cmt. m, n. Thus, evidence that the defendant "did or did not conduct adequately reasonable research or testing before marketing the product may be admissible (but is not necessarily required) regardless of whether the claim is based on negligence, strict liability, or implied warranty of merchantability.

Id. at *4.

Other courts have likewise found that plaintiffs may offer evidence pertaining to these other general theories but that they are all subsumed under the three recognized negligence causes of action. *See Bergman v. Johnson & Johnson*, 2021 WL 5028418, at *4-6 (D. Minn. Oct. 29, 2021) (noting that plaintiff's claims that defendants "negligently inspected, packaged, trained, manufactured, designed, developed, tested, labeled, marketed, and sold" their pelvic mesh products are "amenable to subsumption under Plaintiffs' defective design and failure to warn negligence theories."); *Sykes v. Glaxo-SmithKline*, 484 F. Supp.2d 289, 319 n.32 (E.D. Pa. 2007) (recognizing that "the duty to test would appear logically subsumed within plaintiff's defective design or defective manufacture claims") (citation omitted).

In her response to Defendants' motion, Plaintiff did not cite any authority to support an independent claim of negligence based on a theory of failure to test, inspect, train, study, or

conduct adequate post-market vigilance or surveillance of the TVT-O. While the court finds that Plaintiff may offer evidence related to these theories, they do not constitute independent negligence claims in a product defect case and are subsumed by—or components of—the negligent design defect and/or failure to warn claims.

Moreover, even if Plaintiff could pursue these general negligence theories apart from the three recognized theories, her FAC does not set forth any facts that would plausibly support these claims. For instance, Plaintiff does not explain how Defendants failed to properly train implanting physicians, how Defendants failed to properly test or inspect the TVT-O, or how any such alleged failures purportedly caused her injuries. Nor does she allege what the standard of care supposedly required in terms of "post-launch testing," how Defendants supposedly deviated from that standard, or how any such deviation purportedly caused her claimed injuries. Thus, the court finds that her conclusory allegations pertaining to these theories do not suffice to state independent claims.

CONCLUSION

For the foregoing reasons, the court GRANTS Defendants' Motion for Partial Dismissal of First Amended Complaint [ECF No. 21], and the court hereby limits Plaintiff's negligence claim (Count I) to theories of negligent design defect and failure to warn. Plaintiff's negligent manufacturing defect theory is dismissed, as are Plaintiff's other general negligence theories (i.e., failure to test, inspect, train, study, and conduct adequate post-market vigilance or surveillance of the TVT-O), which the court finds are subsumed by the negligent design defect and failure to warn theories.

Additionally, because Plaintiff has already filed an amended complaint, which was filed more than the 21 days after Defendant filed a motion to dismiss,[3] and because she has not filed a proposed second amended complaint as required by DUCivR 15-1, the court declines to grant leave to file another amended complaint.

No Scheduling Order has yet been entered in this case. Plaintiff, therefore, is directed to propose a schedule to Defendants in the form of a draft Attorney Planning Meeting Report within 14 days.[4]

DATED this 12th day of April, 2023.

BY THE COURT:

DALE A. KIMBALL
United States District Judge

[3] *See* ECF Nos. 18-19. Rule 15 of the Federal Rules of Civil Procedure permits a party to file an amended pleading as a matter of course within 21 days after service of a responsive pleading. Here, Plaintiff's FAC was filed 27 days after Defendants filed their first motion to dismiss. Nevertheless, the court permitted the Amended Complaint to stand. ECF No. 20.

[4] For additional instructions, *see* Order to Propose Schedule, ECF No. 3